(d) *Standard—control panel.* The control panel provides a device (usually a milliammeter or a means for an audible signal to give positive indication of the production of X-rays whenever the X-ray tube is energized. The control panel includes appropriate indicators (labelled control settings and/or meters) which show the physical factors (such as kVp, mA, exposure time or whether timing is automatic) used for the exposure.

(e) *Standard—exposure control switch.* The exposure control switch is of the dead-man type and is so arranged that the operator can stand at least 6 feet from the patient and well away from the useful beam.

(f) *Standard—protection against electrical hazards.* Only shockproof equipment is used. All electrical equipment is grounded.

(g) *Standard—mechanical supporting or restraining devices.* Mechanical supporting or restraining devices are provided so that such devices can be used when a patient must be held in position for radiography.

(h) *Standard—protective gloves and aprons.* Protective gloves and aprons are provided so that when the patient must be held by an individual, that individual is protected with these shielding devices.

(i) *Standard—restriction of the useful beam.* Diaphragms, cones, or adjustable collimators are used to restrict the useful beam to the area of clinical interest.

(j) *Standard—personnel monitoring.* A device which can be worn to monitor radiation exposure (e.g., a film badge) is provided to each individual who operates portable X-ray equipment. The device is evaluated for radiation exposure to the operator at least monthly and appropriate records are maintained by the supplier of portable X-ray services of radiation exposure measured by such a device for each individual.

(k) *Standard—personnel and public protection.* No individual occupationally exposed to radiation is permitted to hold patients during exposures except during emergencies, nor is any other individual regularly used for this service. Care is taken to assure that pregnant women do not assist in portable X-ray examinations.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§ 486.110 Condition for coverage: Inspection of equipment.

Inspections of all X-ray equipment and shielding are made by qualified individuals at intervals not greater than every 24 months.

(a) *Standard—qualified inspectors.* Inspections are made at least every 24 months by a radiation health specialist who is on the staff of or approved by an appropriate State or local government agency.

(b) *Standard—records of inspection and scope of inspection.* The supplier maintains records of current inspections which include the extent to which equipment and shielding are in compliance with the safety standards outlined in § 486.108.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995; 60 FR 50447, Sept. 29, 1995]

Subparts D–F [Reserved]

Subpart G—Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations

SOURCE: 71 FR 31046, May 31, 2006, unless otherwise noted.

§ 486.301 Basis and scope.

(a) *Statutory basis.* (1) Section 1138(b) of the Act sets forth the requirements that an organ procurement organization (OPO) must meet to have its organ procurement services to hospitals covered under Medicare and Medicaid. These include certification as a ''qualified'' OPO and designation as the OPO for a particular service area.

(2) Section 371(b) of the Public Health Service Act sets forth the requirements for certification and the functions that a qualified OPO is expected to perform.

(3) Section 1102 of the Act authorizes the Secretary of Health and Human

Services to make and publish rules and regulations necessary to the efficient administration of the functions that are assigned to the Secretary under the Act.

(4) Section 1871 of the Act authorizes the Secretary to prescribe regulations as may be necessary to carry out the administration of the Medicare program under title XVIII.

(b) *Scope.* This subpart sets forth—

(1) The conditions and requirements that an OPO must meet;

(2) The procedures for certification and designation of OPOs; and

(3) The terms of the agreement with CMS and the basis for and the effect of de-certification.

(4) The requirements for an OPO to be re-certified.

§ 486.302 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. As applied to OPOs, adverse events include but are not limited to transmission of disease from a donor to a recipient, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended recipient.

Agreement cycle refers to the time period of at least 4 years when an agreement is in effect between CMS and an OPO.

Certification means a CMS determination that an OPO meets the requirements for certification at § 486.303.

Death record review means an assessment of the medical chart of a deceased patient to evaluate potential for organ donation.

Decertification means a CMS determination that an OPO no longer meets the requirements for certification at § 486.303.

Designated requestor or effective requestor is an individual (generally employed by a hospital), who is trained to handle or participate in the donation consent process. The designated requestor may request consent for donation from the family of a potential donor or from the individual(s) responsible for making the donation decision in circumstances permitted under State law, provide information about donation to the family or decision-maker(s), or provide support to or collaborate with the OPO in the donation consent process.

Designation means CMS assignment of a geographic service area to an OPO. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act.

Donation service area (DSA) means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area or does not include any part of such an area and that meets the standards of this subpart.

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is recovered for the purpose of transplantation.

Donor after cardiac death (DCD) means an individual who donates after his or her heart has irreversibly stopped beating. A donor after cardiac death may be termed a non-heartbeating or asystolic donor.

Donor document is any documented indication of an individual's choice in regard to donation that meets the requirements of the governing state law.

Eligible death for organ donation means the death of a patient 70 years old or younger, who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits none of the following:

(1) Active infections (specific diagnoses).

(i) Bacterial:

(A) Tuberculosis.

(B) Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis.

(ii) Viral: